

**REMARKS**

Claims 1-57 are pending in the present application. By virtue of this response, claim 1 has been amended. Accordingly, claims 1-57 are currently under consideration. Amendment and cancellation of certain claims is not to be construed as a dedication to the public of any of the subject matter of the claims as previously presented.

Rejections Under 35 U.S.C. § 102(b)

The Office has rejected claims 1, 2, 4, 6-9, 11, 13-16, 19, 21, 22 and 33 as allegedly being anticipated by Gianturco (5,334,210).

In support of the rejection of claims 1, 2, 4, 6-9, 11, 13-16, 19, 21, 22 and 33, the Office Action (Paper No. 15) states the following on pages 2-4:

Gianturco teaches an embolizing device for insertion into an aneurysm. Gianturco teaches at least one detachable self-expanding member 18 configured to be sealed within a membrane 11. The membrane defining a volume and further defining at least one orifice 19 in a surface of the membrane.

The self-expanding member 18 comprises an elongated flexible member, which includes a first configuration (much like the single wire embodiment noted in applicant's specification, paragraph 59) conforming to the internal shape of a positioning catheter 12 having a tubular cross-section. In the first configuration, the member, which is made up of a tungsten/platinum alloy wire, is fed to the site intended through the tubular internal cavity of the catheter. In the second configuration the wire member 18 expands (much like applicant's embodiment, paragraph 59) and is convoluted so as to fill the membrane at the aneurysm site. The member includes a distal end with a J-curve portion and enlarged end segment 25. This preformed hook-shaped portion is at first fed through the internal cavity as an unbent straight portion and when exiting the cavity, the J-curved portion expands or bends (column 4, line 35) or facilitates the bending of the member into a convoluted configuration for filling and expanding the bag at the aneurysm. This bending of the J-curve as it exits the catheter accomplishes or at the very least aids in the self-expanding function of the member.

Re claims 2, and 13-15, the member 18 is taught as attached to a joint 27,34 and 14 and is detachable from this joint. When the member is expanded the member is released from the joint.

Re claim 4, the member 18 is taught as being formed of a tungsten/platinum alloy and includes a J-shaped distal portion taught as expanding or bending into a J-shape, accordingly, the member comprises a shape memory alloy.

Re claim 6, the J-shaped portion of member 18 is taught as being fed through a catheter in a first unbent configuration. This would require the J-shaped portion to be compressed into a catheter conforming shape before it exits the catheter and thus is compressed into a first configuration and then expands at the exit to form the J-shape defined by Gianturco.

Re claims 7-9, the member is taught as having a coil shape (see figure 3, for example). Bending and convoluting the member into a membrane-filling configuration will form a coil or coils of greater diameter. The member itself includes coiled wire with circular cross-sectional areas.

Re claim 11, pushing the member through the catheter stimulates the member and this pushing/stimulation causes the member to convolute and fill the membrane in the second configuration.

Re claim 19, the membrane is taught as having an opening and is connected to the end of the catheter, which is in fluid communication all along and to the proximate end of the catheter. Accordingly, the membrane is in fluid communication with the proximal end of the catheter.

Re claims 21 and 22, the bag is taught as expandable (see column 1, line 46, for example) and taught as made of nylon (column 2, line 1), which is biocompatible.

Remarks

Applicant argues that Gianturco '210 is not applicable since it does not teach at least one self-expanding member. The examiner does not agree. The member of Gianturco is taught as having a J-shaped portion 28 (figure 2). This is a preformed structural element of the member. When this J-shaped portion is fed through the catheter it assumes a "straightened" compressed configuration, and when it exits the catheter the portion "pops" /expands or bends to this preformed J-shaped configuration. This is not a result of the pushing of the member through the catheter but a "memory" of a preformed shape it has. This anticipates the self-expanding limitation of the independent claim. This J-shaped portion further helps in directing the rest of the member to bend and convolute for filling the volume of the bag. Further, the wire itself is coiled into a spiral along its entire length and when this exits the catheter, the wire is bent or "curved" into large convoluted coils and not "fold-ove' itself, like saying for example, a flat sheet of licorice. The end result is a self-expanding convoluted coil structure.

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). (MPEP §2131.)

Independent claim 1 has been amended to recite where "the embolizing device is adapted to reduce a pressure within the volume when reconfigured such that fluid is aspirated through the at least one orifice into the volume". (See specification, [0015] & [0045].) As described in the specification, "[o]nce the balloon begins to expand, an internal pressure within the volume defined by the balloon membrane may begin to drop. The drop in pressure may force the device to aspirate a quantity of surrounding blood and fluids inside the volume." (Specification, [0015].)

On the other hand, Gianturco shows and describes a device having an elongated flexible member 18 "positioned in [a] foldable material bag for filling the bag to an expanded diamond shape" where the bag is generally described as being made of "mated pieces 23 and 24 of untreated

rip stop nylon". (Gianturco, 3: 3-5, 19-21.) Gianturco further describes "[w]hen the flexible elongated member is convoluted and positioned in the folded material occlusion bag, the bag assumes expanded shape 31." (Gianturco, 4: 37-40.) Gianturco fails to show or describe a device which "is adapted to reduce a pressure within the volume when reconfigured such that fluid is aspirated through the at least one orifice into the volume".

Therefore, claim 1 is patentable over Gianturco and dependent claims 2, 4, 6-9, 11, 13-16, 19, 21, 22, and 33 all depend from independent claim 1 and are patentable for at least the same reasons. Accordingly, Applicant respectfully requests the reconsideration and withdrawal of the rejection under 35 U.S.C. § 102(b).

Rejections Under 35 U.S.C. § 102(e)

A. The Office has rejected claims 1, 2, 4-9, 11, 13-16, 19, 21, 22, 26, 33 and 34 as allegedly being anticipated by Van Der Burg et al (WO 00/27292).

In support of the rejection of claims 1, 2, 4-9, 11, 13-16, 19, 21, 22, 26, 33 and 34, the Office Action (Paper No. 15) states the following on pages 6-8:

Van Der Burg et al teach an embolizing device for insertion into an aneurysm. Van Der Burg et al teach a least one detachable self-expanding member 60 (see figures 6-8) configured to be sealed within a membrane 72. The member is defined as self-expanding (page 7, line 16) and, for example, including a structure of struts and linked elements attachable to the end of a delivery catheter. The membrane is defined as acting as a shield between the self-expanding member 65 and the inner surface of a patient's body cavity. The sheath is defined (see page 7, lines 25-33) as having a volume and covering all or part of the member (thus including an opening if partly covering the member).

The self-expanding member 60 comprises a structure such that it includes a first configuration conforming to the internal shape of a positioning catheter (figure 9) having a tubular cross-section. In the first configuration, the member including the sheath/membrane is fed to the site intended through the tubular internal cavity of the catheter. In the second configuration the wire member 60 self expands and fills the membrane at the aneurysm site.

Re claims 2, and 13-15, the member 60 is taught as attached to a joint 73 and is detachable from this joint. When the member is expanded the member is released from the joint.

Re claims 4 and 5, Van Der Burg et al teach that the expandable members of the embodiments of the invention, such as 60, are taught as being formed of a pseudo elastic/memory alloy NiTi alloy or a high strength material (see page 6, lines 18-31) such as stainless steel.

Re claims 6-9, the self-expanding member 60 is taught as being fed through a catheter in a first compressed configuration and then expanded in a second configuration. The physical structure

of the member 60 is taught as comprising a coil 125 (figure 15), a first diameter and then a second diameter (compressed and then expanded) and having a cross-sectional shape including star shaped links (figure 8).

Re claims 11,13-16 and 19, the member 60 is taught as including a hub 72 and this is connected to the guiding member or catheter for placement at the desired site. The catheter would be in fluid communication from a distal end to the proximal end. The member is taught as stimulated by pushing the member through the catheter or stimulated by another form of energy (page 7, line 15-77) such as an electrical energy which, when applied, would erode the connection between the member and the connection.

Re claims 21 and 22, the bag is taught as expandable/distensible and formed of a biocompatible material (page 7, line 30).

Re claims 26,33 and 34, Van Der Burg teaches attaching the expandable member to an outer sheath or balloon (see page 7, lines 18-24).

Van Der Burg shows and describes a device in Figs. 6-8 where “the expandable member 65 ... may also have a sheath 72 disposed around it so as to act as a shield between the expandable member and an inner surface of a patient’s body cavity” where the “sheath 72 may facilitate the sealing function of the occluding member 61, but is primarily intended to prevent damage to either tissue on the inside surface of a body cavity or to the linked elements 66 of the expandable member.” (Van Der Burg, p. 7, lines 25-29.) The sheath is further described where it “may be a weave, braid, film or have any other suitable configuration”. (Van Der Burg, p. 7, lines 30-31.)

However, Van Der Burg fails to show or describe a device which “is adapted to reduce a pressure within the volume when reconfigured such that fluid is aspirated through the at least one orifice into the volume”, as recited in independent claim 1. Therefore, claim 1 is patentable over Van Der Burg and dependent claims 2, 4-9, 11, 13-16, 19, 21, 22, 26, 33, and 34, which all depend ultimately from claim 1, are patentable for at least the same reasons.

Accordingly, Applicant respectfully requests the reconsideration and withdrawal of the rejection under 35 U.S.C. § 102(e).

B. The Office has rejected claims 1-22, 31-33, 35-49, 52-54, 56 and 57 as allegedly being anticipated by Greenhalgh (6,346,117).

In support of the rejection of claims 1-22, 31-33, 35-49, 52-54, 56 and 57, the Office Action (Paper No. 15) states the following on pages 8-10:

Greenhalgh teaches an embolizing device for insertion into an aneurysm. Greenhalgh teaches a least one detachable self-expanding member 78 (see figure 11) configured to be sealed within a membrane 42. The member is defined as self-expanding (column 8, line 39) and includes a self-expanding wire structure in the form of a coil. The membrane is defined as an expandable bag having a volume including an opening (column 7, lines 46-47).

The self-expanding member 78 comprises a structure such that it includes a first configuration conforming to the internal shape of a positioning catheter 26 having a tubular cross-section. In the first configuration, the member including the membrane is fed to the site intended through the tubular internal cavity of the catheter (see figure 5, for example). In the second configuration the wire member 78 self-expands and fills the membrane at the aneurysm site.

Re claims 2, and 13-15, the coil 78 is taught as attached to a feeding wire and "snaked" up the catheter. When the self-expanding member is in place, the wire is released (column 9, line 34).

Re claim 4, Greenhalgh teaches that the expandable member 78 is formed of a great resiliency, high yield stress material and biocompatible.

Re claims 3,5,39,42 and 57, Greenhalgh teaches a stent or expanding member 78 and further teaches NiTi fibers or yarns enclosed or forming part of the bag 42. These NiTi elements are self-expanding for aiding the bag to expand. These constitute the second of the at least two members.

Re claims 6-8,33,40,43,53 and 54, the self-expanding member 78 is taught as being fed through a catheter in a first compressed configuration and then expanded in a second configuration. The physical structure of the member is taught as comprising a coil, a first diameter and then a second diameter (compressed and then expanded), which would touch the inner surface of the membrane. The cross-section of the member would include a circular shape. The final expanded shape would include a spherical shape.

Re claims 11-20,44,45 and 52, pushing the member through the catheter stimulates the member. The member 78 is taught as including a connection and is taught that it is released by mechanical or electrical current means (see column 2, lines 5-25). In the case of the electrical release, a current is passed through the catheter and erodes the connection point at the stent 78.

Re claims 21 and 22, the bag is taught as distensible and biocompatible (column 3, lines 31-38).

Re claims 31 and 32, the bag of Greenhalgh is taught as being formed of 5 to 100 denier and this anticipates these claims.

Re claims 35 and 36, the bag has an orifice of .005 inches, which would accommodate the wire to passing therethrough, which is taught as having a diameter of .005 inches (column 1, line 42).

Re claim 37, Greenhalgh teaches the bag including at least one main opening and being further porous for allowing blood to enter or aspirate into the bag and promote clotting. See column 6, line 65 and column 3, line 3.

Re claim 38, and 46-49, Greenhalgh teaches increasing a volume of a distensible member or bag 42 having at least one opening. Greenhalgh teaches the bag being porous (column 6, line 46) and allowing blood to aspirate (column 3, line 1) therethrough and aid in the clotting of the blood within the bag by electrothrombosis (column 9, lines 22-40). A self-expanding member is placed inside the bag and the bag itself is further provided with NiTi elements.

Greenhalgh shows and describes a device having a bag which "comprises a sleeve 44 defining an enclosed space 46, the sleeve being formed by a circular braid 48 of multifilament yarns 50." (Greenhalgh, 6: 28-31; Fig. 3.) The yarn itself is described as "a fine braid structure having a

relatively high porosity (50%-80%) with relatively small interstices 52 forming pores which allow blood to flow into the enclosed space 46 of bag 42 relatively unimpeded” (Greenhalgh, 6: 41-44.)

Therefore, because of the high porosity of Greenhalgh’s device, the surrounding blood is allowed to flow “relatively unimpeded” into, and presumably out of, the space 46. Greenhalgh’s device thus cannot be said “to reduce a pressure within the volume when reconfigured such that fluid is aspirated through the at least one orifice into the volume”, as recited in claim 1. Because *aspiration occurs via a pressure differential*, Greenhalgh’s device fails to create such a pressure-differential and thus cannot be said to aspirate.

Moreover, independent claim 38 recites “aspirating through the orifice and into the volume a quantity of blood surrounding the distensible membrane”, which is patentable over Greenhalgh for at least the same reasons as independent claim 1. Therefore, independent claims 1 and 38 are patentable over Greenhalgh and dependent claims 2-22, 31-33, 35-37, 39-49, 52, 54, 56, and 57 depend ultimately from claims 1 and 38 and are patentable for at least the same reasons.

Accordingly, Applicant respectfully requests the reconsideration and withdrawal of the rejection under 35 U.S.C. § 102(e).

Allowable Subject Matter

The Office has indicated that claims 23-25, 27-30, 50, 51, and 55 objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Applicant acknowledges the allowable subject matter with thanks. However, Applicant contends that in light of the remarks above, all pending claims are allowable and respectfully requests allowance therefor.

CONCLUSION

Applicant has, by way of the amendments and remarks presented herein, made a sincere effort to overcome rejections and address all issues that were raised in the outstanding Office Action. Accordingly, reconsideration and allowance of the pending claims are respectfully requested. If it is determined that a telephone conversation would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

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Respectfully submitted,

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